

114TH CONGRESS  
1ST SESSION

# H. R. 1599

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## AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with respect to food produced from, containing, or consisting of a bioengineered organism, the labeling of natural foods, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the  
3 “Safe and Accurate Food Labeling Act of 2015”.

4 (b) **TABLE OF CONTENTS.**—The table of contents of  
5 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Savings clause.

**TITLE I—FOOD SAFETY AFFIRMATION FOR CERTAIN PLANT  
PRODUCTS**

**Subtitle A—Food and Drug Administration**

Sec. 101. Consultation process.

**Subtitle B—Department of Agriculture**

Sec. 111. Regulation.

Sec. 112. Regulations.

Sec. 113. Preemption.

Sec. 114. Rule of construction.

Sec. 115. Implementation report.

**TITLE II—GENETIC ENGINEERING CERTIFICATION**

Sec. 201. Genetic engineering certification.

Sec. 202. Regulations.

Sec. 203. Preemption.

Sec. 204. Applicability.

**TITLE III—NATURAL FOODS**

Sec. 301. Labeling of natural foods.

Sec. 302. Regulations.

Sec. 303. Preemption.

Sec. 304. Effective date.

6 **SEC. 2. SAVINGS CLAUSE.**

7 Nothing in this Act (or the amendments made by this  
8 Act) is intended to alter or affect the authorities or regu-  
9 latory programs, policies, and procedures otherwise avail-  
10 able to, or the definitions used by, the Food and Drug  
11 Administration under the Federal Food, Drug, and Cos-  
12 metic Act (21 U.S.C. 301 et seq.) or the Animal and Plant

1 Health Inspection Service under the Plant Protection Act  
2 (7 U.S.C. 7701 et seq.), to ensure the safety of the food  
3 supply and the protection of plant health.

4 **TITLE I—FOOD SAFETY AFFIR-**  
5 **MATION FOR CERTAIN PLANT**  
6 **PRODUCTS**

7 **Subtitle A—Food and Drug**  
8 **Administration**

9 **SEC. 101. CONSULTATION PROCESS.**

10 Chapter IV of the Federal Food, Drug, and Cosmetic  
11 Act is amended by inserting after section 423 of such Act  
12 (21 U.S.C. 350l) the following:

13 **“SEC. 424. FOOD DERIVED FROM NEW PLANT VARIETIES.**

14 “(a) IN GENERAL.—The Secretary shall continue to  
15 administer the consultation process established under the  
16 Food and Drug Administration’s policy statement entitled  
17 ‘Statement of Policy: Food Derived from New Plant Vari-  
18 eties’ published in the Federal Register on May 29, 1992  
19 (57 Fed. Reg. 22,984).

20 “(b) DETERMINATION OF MATERIAL DIFFERENCE  
21 BETWEEN FOOD FROM GENETICALLY ENGINEERED  
22 PLANTS AND COMPARABLE FOODS.—

23 “(1) IN GENERAL.—For purposes of subsection  
24 (a), the use of genetic engineering does not, by  
25 itself, constitute information that is material for

1 purposes of determining whether there is a dif-  
2 ference between a food produced from, containing,  
3 or consisting of a genetically engineered plant and a  
4 comparable food.

5 “(2) LABELING REQUIRED.—The Secretary  
6 may require that the labeling of a food produced  
7 from, containing, or consisting of a genetically engi-  
8 neered plant contain a statement to adequately in-  
9 form consumers of a difference between the food so  
10 produced and its comparable food if the Secretary  
11 determines that—

12 “(A) there is a material difference in the  
13 functional, nutritional, or compositional charac-  
14 teristics, allergenicity, or other attributes be-  
15 tween the food so produced and its comparable  
16 food; and

17 “(B) the disclosure of such material dif-  
18 ference is necessary to protect public health and  
19 safety or to prevent the label or labeling of the  
20 food so produced from being false or misleading  
21 in any particular.”.

1                   **Subtitle B—Department of**  
2                   **Agriculture**

3 **SEC. 111. REGULATION.**

4           The Plant Protection Act (7 U.S.C. 7701 et seq.) is  
5 amended by adding at the end the following new subtitle:

6           **“Subtitle F—Coordination of Food**  
7           **Safety and Agriculture Programs**

8           **“SEC. 461. NOTIFICATION RELATING TO CERTAIN GENETI-**  
9                                   **CALLY ENGINEERED PLANTS.**

10           “(a) IN GENERAL.—Subject to subsection (b), it shall  
11 be unlawful to sell or offer for sale in interstate commerce  
12 a nonregulated genetically engineered plant for use or ap-  
13 plication in food or a food produced from, containing, or  
14 consisting of a nonregulated genetically engineered plant  
15 unless—

16                   “(1)(A) the Secretary of Health and Human  
17           Services notified the entity seeking evaluation of a  
18           food produced from, containing, or consisting of the  
19           genetically engineered plant in writing that the Sec-  
20           retary of Health and Human Services, in evaluating  
21           the food from the genetically engineered plant  
22           through the consultation process referred to in sec-  
23           tion 424(a) of the Federal Food, Drug, and Cos-  
24           metic Act, has no objections to the entity’s deter-  
25           mination that food produced from, containing, or

1 consisting of the genetically engineered plant that is  
2 the subject of the notification is safe for use by hu-  
3 mans or animals, as applicable, and lawful under the  
4 Federal Food, Drug, and Cosmetic Act; and

5 “(B) the entity seeking evaluation of a food  
6 produced from, containing, or consisting of the ge-  
7 netically engineered plant submits to the Secretary  
8 of Agriculture the notification of the finding of the  
9 Secretary of Health and Human Services under sub-  
10 paragraph (A); or

11 “(2) before the date of the enactment of the  
12 Safe and Accurate Food Labeling Act of 2015, the  
13 Secretary of Health and Human Services—

14 “(A) considered the consultation process  
15 referred to in section 424(a) of the Federal  
16 Food, Drug, and Cosmetic Act with respect to  
17 such genetically engineered plant to be com-  
18 plete;

19 “(B) notified the consulting party in writ-  
20 ing that all questions with respect to the safety  
21 of food produced from, containing, or consisting  
22 of the genetically engineered plant have been re-  
23 solved; and

1           “(C) published such notification on the  
2           public Internet website of the Food and Drug  
3           Administration.

4           “(b) EXCEPTIONS.—Notwithstanding subsection (a),  
5 this section does not apply with respect to the sale or of-  
6 fering for sale in interstate commerce of a genetically engi-  
7 neered plant—

8           “(1) for the purpose of research or development  
9           testing, including—

10           “(A) testing conducted to generate data  
11           and information that could be used in a submis-  
12           sion to the Secretary under this title or other  
13           regulatory submission; or

14           “(B) multiplication of seed or hybrid and  
15           variety development conducted before submit-  
16           ting a notification under subsection (a)(1)(B);

17           “(2) solely because a processing aid or enzyme  
18           produced from the genetically engineered plant is in-  
19           tended to be used to produce food; or

20           “(3) solely because the genetically engineered  
21           plant is used as a nutrient source for microorga-  
22           nisms.

23           “(c) RULE OF CONSTRUCTION.—Nothing in sub-  
24           section (b)(1) may be construed as authorizing the sale  
25           or offering for sale in interstate commerce of a nonregu-

1 lated genetically engineered plant for use or application  
2 in food or a food produced from, containing, or consisting  
3 of a nonregulated genetically engineered plant.

4 “(d) PUBLIC DISCLOSURE.—

5 “(1) IN GENERAL.—Subject to paragraph (2),  
6 the Secretary of Agriculture shall publish on the  
7 public Internet website of the Department of Agri-  
8 culture, and update as necessary, a registry that in-  
9 cludes—

10 “(A) a list of each nonregulated genetically  
11 engineered plant intended for a use or applica-  
12 tion in food that may be sold or offered for sale  
13 in interstate commerce, in accordance with sub-  
14 section (a);

15 “(B) the petitions submitted to, and deter-  
16 minations made by, the Secretary of Agri-  
17 culture with respect to such a plant; and

18 “(C) the notifications of findings issued by  
19 the Secretary of Health and Human Services  
20 with respect to such a plant or the use or appli-  
21 cation of such a plant in food.

22 “(2) TRADE SECRETS AND CONFIDENTIAL IN-  
23 FORMATION.—Notwithstanding paragraph (1), noth-  
24 ing in this section shall be construed to alter the  
25 protections offered by laws, regulations, and policies

1 governing disclosure of confidential commercial or  
2 trade secret information, and any other information  
3 exempt from disclosure pursuant to section 552(b)  
4 of title 5, United States Code, as such provisions  
5 would be applied to the documents and information  
6 referred to in subparagraphs (A) through (C) of  
7 paragraph (1).

8 “(e) IMPORTED FOOD.—In the case of food imported  
9 into the United States that is food produced from, con-  
10 taining, or consisting of a plant that meets the definition  
11 of a nonregulated genetically engineered plant or a plant  
12 that, if sold in interstate commerce, would be subject to  
13 regulation under part 340 of title 7, Code of Federal Reg-  
14 ulations (or any successor regulations), the provisions of  
15 this section shall apply to such food in the same manner  
16 and to the same extent as such provisions apply to a food  
17 that is not so imported.

18 **“SEC. 462. DEFINITIONS.**

19 “In this subtitle:

20 “(1) FOOD.—The term ‘food’ has the meaning  
21 given such term in section 201(f) of the Federal  
22 Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)).

23 “(2) NONREGULATED GENETICALLY ENGI-  
24 NEERED PLANT.—The term ‘nonregulated geneti-

1 cally engineered plant’ means a genetically engi-  
2 neered plant—

3 “(A) for which the Secretary of Agri-  
4 culture has approved a petition under section  
5 340.6 of title 7, Code of Federal Regulations  
6 (or any successor regulations), for a determina-  
7 tion that the genetically engineered plant should  
8 not be regulated under this Act; or

9 “(B) that—

10 “(i) is not subject to regulation as a  
11 plant pest under this Act;

12 “(ii) contains genetic material from a  
13 different species; and

14 “(iii) has been modified through in  
15 vitro recombinant deoxyribonucleic acid  
16 (DNA) techniques.”.

17 **SEC. 112. REGULATIONS.**

18 Not later than 1 year after the date of the enactment  
19 of this Act, the Secretary of Agriculture shall promulgate  
20 interim final regulations to carry out the amendments  
21 made by section 111.

22 **SEC. 113. PREEMPTION.**

23 Regardless of whether regulations have been promul-  
24 gated under section 112, beginning on the date of the en-  
25 actment of this Act, no State or political subdivision of

1 a State may directly or indirectly establish under any au-  
2 thority or continue in effect as to any food in interstate  
3 commerce any requirement with respect to the sale or of-  
4 fering for sale in interstate commerce of a genetically engi-  
5 neered plant for use or application in food that is not iden-  
6 tical to the requirement of section 461 of the Plant Protec-  
7 tion Act (as added by section 111 of this Act).

8 **SEC. 114. RULE OF CONSTRUCTION.**

9 Nothing in the amendments made by this subtitle is  
10 intended to alter or affect the ability of—

11 (1) the Secretary of Health and Human Serv-  
12 ices to take enforcement actions with respect to a  
13 violation of the Federal Food, Drug, and Cosmetic  
14 Act (21 U.S.C. 301 et seq.), including section 301  
15 of such Act (21 U.S.C. 331); or

16 (2) the Secretary of Agriculture to take enforce-  
17 ment actions with respect to a violation of the Plant  
18 Protection Act (7 U.S.C. 7701 et seq.), including  
19 section 411 of such Act (7 U.S.C. 7711).

20 **SEC. 115. IMPLEMENTATION REPORT.**

21 (a) STUDY.—Not later than 1 year after the date of  
22 the enactment of this Act, the Secretary of Agriculture  
23 and the Secretary of Health and Human Services shall  
24 jointly submit to Congress a report evaluating the  
25 progress made in the implementation of subtitle F of the

1 Plant Protection Act, as added by section 111. Such re-  
2 port shall include—

3 (1) an analysis of plants over which regulatory  
4 oversight under such subtitle is required;

5 (2) an analysis of the extent to which the provi-  
6 sions of such subtitle establish an appropriate scope  
7 of regulatory oversight for the Animal and Plant  
8 Health Inspection Service and the Food and Drug  
9 Administration, including their oversight of public  
10 research programs; and

11 (3) any potential changes to the Plant Protec-  
12 tion Act that would better facilitate implementation  
13 of a coordinated, predictable, and efficient science-  
14 based regulatory process.

15 (b) COORDINATION WITH OTHER EFFORTS TO MOD-  
16 ERNIZE REGULATION.—The report under subsection (a)  
17 shall be prepared, to the greatest extent practicable, in  
18 accordance with the process described in the memorandum  
19 issued by the Executive Office of the President on July  
20 2, 2015, entitled “Modernizing the Regulatory System for  
21 Biotechnology Products”, including the directive specified  
22 in such memorandum to update the “Coordinated Frame-  
23 work for Regulation of Biotechnology” published by the  
24 Executive Office of the President, Office of Science and

1 Technology Policy, in the Federal Register on June 26,  
2 1986 (51 Fed. Reg. 23302).

3 **TITLE II—GENETIC**  
4 **ENGINEERING CERTIFICATION**

5 **SEC. 201. GENETIC ENGINEERING CERTIFICATION.**

6 The Agricultural Marketing Act of 1946 (7 U.S.C.  
7 1621 et seq.) is amended by adding at the end the fol-  
8 lowing new subtitle:

9 **“Subtitle E—Genetic Engineering**  
10 **Certification**

11 **“SEC. 291. DEFINITIONS.**

12 “In this subtitle:

13 “(1) The term ‘certifying agent’ means the  
14 chief executive officer of a State or, in the case of  
15 a State that provides for the statewide election of an  
16 official to be responsible solely for the administra-  
17 tion of the agricultural operations of the State, such  
18 official, and any person (including a private entity)  
19 who is accredited by the Secretary as a certifying  
20 agent for the purpose of certifying a covered product  
21 as a product, the labeling of which may indicate  
22 whether the product is produced with or without the  
23 use of genetic engineering.

24 “(2) The term ‘covered product’ means—

1           “(A) an agricultural product, whether raw  
2           or processed (including any product derived  
3           from livestock that is marketed in the United  
4           States for consumption by humans or other ani-  
5           mals);

6           “(B) any other food (as defined in section  
7           201 of the Federal Food, Drug, and Cosmetic  
8           Act) not derived from an agricultural product;  
9           and

10           “(C) seed or other propagative material.

11           “(3) The term ‘genetically engineered plant’ re-  
12           fers to a plant or plant product (as those terms are  
13           defined in section 403 of the Plant Protection Act  
14           (7 U.S.C. 7702)), if—

15           “(A) it contains genetic material that has  
16           been modified through in vitro recombinant  
17           deoxyribonucleic acid (DNA) techniques; and

18           “(B) the modification could not otherwise  
19           be obtained using conventional breeding tech-  
20           niques.

21           “(4) The term ‘comparable food’ means, with  
22           respect to a covered product produced from, con-  
23           taining, or consisting of a genetically engineered  
24           plant—

25           “(A) the parental variety of the plant;

1           “(B) another commonly consumed variety  
2           of the plant; or

3           “(C) a commonly consumed covered prod-  
4           uct with properties comparable to the covered  
5           product produced from, containing, or con-  
6           sisting of the genetically engineered plant.

7           “(5) The term ‘handle’ means to sell, process,  
8           or package covered products.

9           “(6) The term ‘producer’ means a person who  
10          engages in the business of growing or producing cov-  
11          ered products.

12          “(7) The term ‘Secretary’ means the Secretary  
13          of Agriculture, acting through the Agricultural Mar-  
14          keting Service.

15   **“SEC. 291A. NATIONAL GENETICALLY ENGINEERED FOOD**  
16                           **CERTIFICATION PROGRAM.**

17          “(a) IN GENERAL.—The Secretary shall establish a  
18          voluntary genetically engineered food certification pro-  
19          gram for covered products with respect to the use of ge-  
20          netic engineering in the production of such products, as  
21          provided for in this subtitle. The Secretary shall establish  
22          the requirements and procedures as the Secretary deter-  
23          mines are necessary to carry out such program.

24          “(b) CONSULTATION.—In developing the program  
25          under subsection (a), the Secretary shall consult with such

1 other parties as are necessary to develop such program  
2 to ensure that producers or handlers seeking to make  
3 claims under section 291B or 291C are certified to make  
4 such claims.

5 “(c) CERTIFICATION.—The Secretary shall imple-  
6 ment the program established under subsection (a)  
7 through certifying agents. Such certifying agents may cer-  
8 tify that covered products were or were not produced with  
9 the use of genetic engineering or a genetically engineered  
10 plant, in accordance with this subtitle.

11 “(d) SEAL.—The Secretary shall establish a seal to  
12 identify covered products in interstate commerce using  
13 terminology the Secretary considers appropriate for cov-  
14 ered products certified under this title, including termi-  
15 nology commonly used in interstate commerce or estab-  
16 lished by the Secretary in regulations.

17 **“SEC. 291B. NATIONAL STANDARDS FOR LABELING NON-**  
18 **GENETICALLY ENGINEERED FOOD.**

19 “(a) IN GENERAL.—To be sold or labeled as a cov-  
20 ered product produced without the use of genetic engineer-  
21 ing—

22 “(1) the covered product shall—

23 “(A) be subject to supply chain process  
24 controls that address—

1           “(i) the producer planting seed that is  
2           not genetically engineered;

3           “(ii) the producer keeping the crop  
4           separated during growth, harvesting, stor-  
5           age, and transportation; and

6           “(iii) persons in direct contact with  
7           such crop or products derived from such  
8           crop during transportation, storage, or  
9           processing keeping the product separated  
10          from other products that are, or are de-  
11          rived from, genetically engineered plants;  
12          and

13          “(B) be produced and handled in compli-  
14          ance with a nongenetically engineered food plan  
15          developed and approved in accordance with sub-  
16          section (c);

17          “(2) in the case of a covered product derived  
18          from livestock that is marketed in the United States  
19          for human consumption, the covered product and the  
20          livestock, products consumed by such livestock, and  
21          products used in processing the products consumed  
22          by such livestock shall be produced without the use  
23          of products derived from genetic engineering; and

24          “(3) labeling or advertising material on, or in  
25          conjunction with, such covered product shall not

1 suggest either expressly or by implication that covered  
2 products developed without the use of genetic  
3 engineering are safer or of higher quality than covered  
4 products produced from, containing, or consisting  
5 of a genetically engineered plant.

6 “(b) EXCEPTIONS.—A covered product shall not be  
7 considered as not meeting the criteria specified in sub-  
8 section (a) solely because the covered product—

9 “(1) is manufactured or processed using a ge-  
10 netically engineered microorganism or a processing  
11 aid or enzyme;

12 “(2) is derived from microorganisms that con-  
13 sumed a nutrient source produced from, containing,  
14 or consisting of a genetically engineered plant; or

15 “(3) is an approved substance on the National  
16 List established under section 2118 of the Organic  
17 Foods Production Act of 1990 (7 U.S.C. 6517).

18 “(c) NONGENETICALLY ENGINEERED FOOD PLAN.—

19 “(1) IN GENERAL.—A producer or handler  
20 seeking certification under this section shall submit  
21 a nongenetically engineered food plan to the certi-  
22 fying agent and such plan shall be reviewed by the  
23 certifying agent who shall determine if such plan  
24 meets the requirements of this section.



1           “(1) the covered product shall be produced and  
2 handled in compliance with a genetically engineered  
3 food plan developed and approved in accordance with  
4 subsection (b); and

5           “(2) the labeling of, or advertising material on,  
6 or in conjunction with, such covered product shall—

7                   “(A) not expressly or impliedly claim that  
8 a covered product developed with the use of ge-  
9 netic engineering is safer or of higher quality  
10 solely because the covered product is a product  
11 developed with the use of genetic engineering;

12                   “(B) not make any claims that are false or  
13 misleading; and

14                   “(C) contain such information as the Sec-  
15 retary considers appropriate.

16           “(b) GENETICALLY ENGINEERED FOOD PLAN.—

17                   “(1) IN GENERAL.—A producer or handler  
18 seeking certification under this section shall submit  
19 a genetically engineered food plan to the certifying  
20 agent and such plan shall be reviewed by the certi-  
21 fying agent who shall determine if such plan meets  
22 the requirements of this section.

23                   “(2) CONTENTS.—A genetically engineered food  
24 plan shall contain a description of—

1           “(A) the procedures that will be followed  
2           to assure compliance with this section;

3           “(B) a description of the monitoring  
4           records that will be maintained; and

5           “(C) any corrective actions that will be im-  
6           plemented in the event there is a deviation from  
7           the plan.

8           “(3) AVAILABILITY.—The genetically engi-  
9           neered food plan and the records maintained under  
10          the plan shall be available for review and copying by  
11          the Secretary or a certifying agent.

12          “(c) PROHIBITION AGAINST RESTRICTING CERTAIN  
13          DISCLOSURES.—With respect to a covered product that  
14          otherwise meets the criteria specified in subsection (a), the  
15          Secretary may not prevent a person—

16                 “(1) from disclosing voluntarily on the labeling  
17                 of such a covered product developed with the use of  
18                 genetic engineering the manner in which the product  
19                 has been modified to express traits or characteristics  
20                 that differ from its comparable food; or

21                 “(2) from disclosing in advertisements, on the  
22                 Internet, in response to consumer inquiries, or on  
23                 other communications, other than in the labeling,  
24                 that a covered product was developed with the use  
25                 of genetic engineering.

1 **“SEC. 291D. IMPORTED PRODUCTS.**

2 “Imported covered products may be sold or labeled  
3 as produced with or without the use of genetic engineering  
4 if the Secretary determines that such products have been  
5 produced and handled under a genetic engineering certifi-  
6 cation program that provides safeguards and guidelines  
7 governing the production and handling of such products  
8 that are at least equivalent to the requirements of this  
9 subtitle.

10 **“SEC. 291E. ACCREDITATION PROGRAM.**

11 “(a) IN GENERAL.—The Secretary shall establish  
12 and implement a program to accredit a governing State  
13 official, and any private person, that meets the require-  
14 ments of this section as a certifying agent for the purpose  
15 of certifying a covered product as having been produced  
16 with or without the use of genetic engineering or a geneti-  
17 cally engineered plant, in accordance with this subtitle.

18 “(b) REQUIREMENTS.—To be accredited as a certi-  
19 fying agent under this section, a governing State official  
20 or private person shall—

21 “(1) prepare and submit to the Secretary an  
22 application for such accreditation;

23 “(2) have sufficient expertise in agricultural  
24 production and handling techniques as determined  
25 by the Secretary; and



1           “(B) make available to the Secretary, on  
2 request by the Secretary, all records associated  
3 with the covered product.

4           “(2) CERTIFYING AGENTS.—

5           “(A) IN GENERAL.—A certifying agent  
6 shall—

7           “(i) maintain all records concerning  
8 the activities of the certifying agent with  
9 respect to the certification of covered prod-  
10 ucts under this subtitle in a manner pre-  
11 scribed by the Secretary; and

12           “(ii) make available to the Secretary,  
13 on request by the Secretary, all records as-  
14 sociated with such activities.

15           “(B) TRANSFERENCE OF RECORDS.—If a  
16 private person that was certified under this sub-  
17 title is dissolved or loses accreditation, all  
18 records and copies of records concerning the ac-  
19 tivities of the person under this subtitle shall be  
20 transferred to the Secretary.

21           “(b) INVESTIGATIONS.—

22           “(1) IN GENERAL.—The Secretary may take  
23 such investigative actions as the Secretary considers  
24 to be necessary—

1           “(A) to verify the accuracy of any informa-  
2           tion reported or made available under this sub-  
3           title; and

4           “(B) to determine whether a person cov-  
5           ered by this subtitle has committed a violation  
6           of any provision of this subtitle, including an  
7           order or regulation promulgated by the Sec-  
8           retary pursuant to this subtitle.

9           “(2) SPECIFIC INVESTIGATIVE POWERS.—In  
10          carrying out this subtitle, the Secretary may—

11           “(A) administer oaths and affirmations;

12           “(B) subpoena witnesses;

13           “(C) compel attendance of witnesses;

14           “(D) take evidence; and

15           “(E) require the production of any records  
16          required to be maintained under this subtitle  
17          that are relevant to an investigation.

18          “(c) VIOLATIONS OF SUBTITLE.—

19           “(1) FAILURE TO PROVIDE INFORMATION.—

20          Any person covered by this subtitle who, after notice  
21          and an opportunity to be heard, has been found by  
22          the Secretary to have failed or refused to provide ac-  
23          curate information (including a delay in the timely  
24          delivery of such information) required by the Sec-

1       retary under this subtitle, shall be assessed a civil  
2       penalty of not more than \$10,000.

3               “(2) MISUSE OF LABEL.—

4                       “(A) IN GENERAL.—Any person who, after  
5       notice and an opportunity to be heard, is found  
6       by the Secretary to have knowingly sold or la-  
7       beled any covered product as having been pro-  
8       duced with or without the use of genetic engi-  
9       neering or a genetically engineered plant, except  
10      in accordance with this subtitle, shall be as-  
11     sessed a civil penalty of not more than \$10,000.

12                      “(B) CONTINUING VIOLATION.—Each day  
13      during which a violation described in subpara-  
14      graph (A) occurs shall be considered to be a  
15      separate violation.

16               “(3) INELIGIBILITY.—

17                      “(A) IN GENERAL.—Except as provided in  
18      subparagraph (C), any person that carries out  
19      an activity described in subparagraph (B), after  
20      notice and an opportunity to be heard, shall not  
21      be eligible, for the 5-year period beginning on  
22      the date of the occurrence, to receive a certifi-  
23      cation under this subtitle with respect to any  
24      covered product.

1           “(B) DESCRIPTION OF ACTIVITIES.—An  
2 activity referred to in subparagraph (A) is—

3           “(i) making a false statement;

4           “(ii) a violation described in para-  
5 graph (2)(A);

6           “(iii) attempting to have a label indi-  
7 cating that a covered product has been  
8 produced with or without the use of genetic  
9 engineering or a genetically engineered  
10 plant affixed to a covered product that a  
11 person knows, or should have reason to  
12 know, to have been produced in a manner  
13 that is not in accordance with this subtitle;  
14 or

15           “(iv) otherwise violating the purposes  
16 of the genetically engineered food certifi-  
17 cation program established under section  
18 291A, as determined by the Secretary.

19           “(C) WAIVER.—Notwithstanding subpara-  
20 graph (A), the Secretary may modify or waive  
21 a period of ineligibility under this paragraph if  
22 the Secretary determines that the modification  
23 or waiver is in the best interests of the geneti-  
24 cally engineered food certification program es-  
25 tablished under section 291A.

1           “(4) REPORTING OF VIOLATIONS.—A certifying  
2 agent shall immediately report any violation of this  
3 subtitle to the Secretary.

4           “(5) CEASE-AND-DESIST ORDERS.—

5           “(A) IN GENERAL.—The Secretary may,  
6 after providing notice and an opportunity to be  
7 heard, issue an order, require any person who  
8 the Secretary reasonably believes is selling or  
9 labeling a covered product in violation of this  
10 subtitle to cease and desist from selling or la-  
11 beling such covered product as having been pro-  
12 duced with or without the use of genetic engi-  
13 neering or a genetically engineered plant.

14           “(B) FINAL AND CONCLUSIVE.—The order  
15 of the Secretary imposing a cease-and-desist  
16 order under this paragraph shall be final and  
17 conclusive unless the affected person files an  
18 appeal from the Secretary’s order with the ap-  
19 propriate district court of the United States not  
20 later than 30 days after the date of the  
21 issuance of the order.

22           “(6) VIOLATIONS BY CERTIFYING AGENT.—A  
23 certifying agent that is a private person that violates  
24 the provisions of this subtitle or falsely or neg-  
25 ligently certifies any covered product that does not

1 meet the terms and conditions of the genetically en-  
2 gineered food certification program established  
3 under section 291A, as determined by the Secretary,  
4 shall, after notice and an opportunity to be heard—

5 “(A) lose accreditation as a certifying  
6 agent under this subtitle; and

7 “(B) be ineligible to be accredited as a cer-  
8 tifying agent under this subtitle for a period of  
9 not less than 3 years, beginning on the date of  
10 the determination.

11 “(7) SUSPENSION.—

12 “(A) IN GENERAL.—The Secretary may,  
13 after first providing the certifying agent notice  
14 and an opportunity to be heard, suspend the ac-  
15 creditation of the certifying agent for a period  
16 specified in subparagraph (B) for a violation of  
17 this subtitle.

18 “(B) PERIOD OF SUSPENSION.—The pe-  
19 riod of a suspension under subparagraph (A)  
20 shall terminate on the date the Secretary makes  
21 a final determination with respect to the viola-  
22 tion that is the subject of the suspension.

23 “(8) ENFORCEMENT BY ATTORNEY GEN-  
24 ERAL.—On request of the Secretary, the Attorney  
25 General may bring a civil action against a person in

1 a district court of the United States to enforce this  
2 subtitle or a requirement or regulation prescribed, or  
3 an order issued, under this subtitle. The action may  
4 be brought in the judicial district in which the per-  
5 son does business or in which the violation occurred.

6 **“SEC. 291G. AUTHORIZATION OF APPROPRIATIONS; FEES.**

7 “(a) AUTHORIZATION OF APPROPRIATIONS.—There  
8 are authorized to be appropriated to establish the geneti-  
9 cally engineered food certification program under section  
10 291A, \$2,000,000, to remain available until expended.

11 “(b) FEES.—

12 “(1) IN GENERAL.—Upon establishment of the  
13 genetically engineered food certification program  
14 under section 291A, the Secretary shall establish by  
15 notice, charge, and collect fees to cover the esti-  
16 mated costs to the Secretary of carrying out this  
17 subtitle.

18 “(2) AVAILABILITY.—Fees collected under  
19 paragraph (1) shall be deposited into a fund in the  
20 Treasury of the United States and shall remain  
21 available until expended, subject to appropriation, to  
22 carry out this subtitle.”.

1 **SEC. 202. REGULATIONS.**

2 In promulgating regulations to carry out the amend-  
3 ments made by section 201, the Secretary of Agriculture  
4 shall—

5 (1) provide a process to account for certified  
6 nongenetically engineered covered products con-  
7 taining material from genetically engineered plants  
8 due to the inadvertent presence of such material;

9 (2) to the greatest extent practicable, establish  
10 consistency between the certification programs es-  
11 tablished under subtitle E of the Agricultural Mar-  
12 keting Act of 1946 (as added by section 201 of this  
13 Act), the organic certification program established  
14 under the Organic Foods Production Act of 1990 (7  
15 U.S.C. 6501 et seq.), and other voluntary labeling  
16 programs administered by the Secretary;

17 (3) with respect to regulations for covered prod-  
18 ucts intended for consumption by non-food animals,  
19 take into account the inherent differences between  
20 food intended for animal and human consumption,  
21 including the essential vitamins, minerals, and  
22 micronutrients required to be added to animal food  
23 to formulate a complete and balanced diet; and

24 (4) provide a process for requesting and grant-  
25 ing exemptions from the requirements of subtitle E  
26 of the Agricultural Marketing Act of 1946 (as added

1 by section 201 of this Act) under conditions estab-  
2 lished by the Secretary.

3 **SEC. 203. EFFECTIVE DATE; PREEMPTION.**

4 (a) **EFFECTIVE DATE.**—Regardless of whether regu-  
5 lations have been promulgated under section 202 of this  
6 Act, the amendments made by section 201 shall take effect  
7 beginning on the date of the enactment of this Act.

8 (b) **PROHIBITIONS AGAINST MANDATORY LABELING**  
9 **OF FOOD DEVELOPED USING GENETIC ENGINEERING.**—

10 (1) **IN GENERAL.**—Subject to paragraph (2), no  
11 State or political subdivision of a State may directly  
12 or indirectly establish under any authority or con-  
13 tinue in effect as to any covered product (as defined  
14 in section 291 of the Agricultural Marketing Act of  
15 1946, as added by section 201 of this Act) in inter-  
16 state commerce, any requirement for the labeling of  
17 a covered product indicating the product as having  
18 been produced from, containing, or consisting of a  
19 genetically engineered plant, including any require-  
20 ments for claims that a covered product is or con-  
21 tains an ingredient that was produced from, con-  
22 tains, or consists of a genetically engineered plant.

23 (2) **EXCEPTION.**—Notwithstanding paragraph  
24 (1), a State (or a political subdivision thereof) may  
25 establish either of the following voluntary programs

1 for the regulation of claims described in such para-  
2 graph:

3 (A) A program that relates to voluntary  
4 claims to which paragraph (1) of section 204(a)  
5 of this Act applies.

6 (B) A program that—

7 (i) is voluntary;

8 (ii) is accredited by the Secretary pur-  
9 suant to section 291E of the Agricultural  
10 Marketing Act of 1946 (as added by sec-  
11 tion 201 of this Act); and

12 (iii) establishes standards that are  
13 identical to the standards established  
14 under section 291B or 291C of the Agri-  
15 cultural Marketing Act of 1946, as appli-  
16 cable (as added by section 201 of this Act).

17 (c) **RULE OF CONSTRUCTION.**—For the sole purpose  
18 of subsection (b)(1), a covered product derived from live-  
19 stock that consumed genetically engineered plants shall be  
20 deemed as having been produced from, containing, or con-  
21 sisting of a genetically engineered plant.

22 **SEC. 204. APPLICABILITY.**

23 (a) **EXISTING CLAIMS.**—A voluntary claim made with  
24 respect to whether a covered product (as defined in section  
25 291 of the Agricultural Marketing Act of 1946, as added

1 by section 201 of this Act) was produced with or without  
2 the use of genetic engineering or genetically engineered  
3 plants before the date of the enactment of this Act—

4 (1) may be made for such a product during the  
5 36-month period that begins on the date of the en-  
6 actment of this Act; and

7 (2) after the expiration of such 36-month pe-  
8 riod, may be made so long as the labels associated  
9 with such a claim meet the standards specified in  
10 section 291B or 291C of the Agricultural Marketing  
11 Act of 1946, as applicable (as added by section 201  
12 of this Act).

13 (b) ORGANIC CERTIFICATION.—In the case of a cov-  
14 ered product (as defined in section 291 of the Agricultural  
15 Marketing Act of 1946, as added by section 201 of this  
16 Act) produced by a farm or handling operation that is cer-  
17 tified as an organic farm or handling operation under the  
18 Organic Foods Production Act of 1990 (7 U.S.C. 6501  
19 et seq.), such product is deemed to be certified as a prod-  
20 uct produced without the use of genetic engineering under  
21 the genetically engineered food certification program es-  
22 tablished under section 291A of the Agricultural Mar-  
23 keting Act of 1946 (as added by section 201 of this Act).

1       **TITLE III—NATURAL FOODS**

2       **SEC. 301. LABELING OF NATURAL FOODS.**

3           Section 403 of the Federal Food, Drug, and Cosmetic  
4 Act (21 U.S.C. 343) is amended by adding at the end the  
5 following:

6           “(z)(1) If its labeling contains an express or implied  
7 claim that the food is ‘natural’ unless the claim is made  
8 in accordance with subparagraph (2).

9           “(2) A claim described in subparagraph (1) may be  
10 made only if the claim uses terms that have been defined  
11 by, and the food meets the requirements that have been  
12 established in, regulations promulgated to carry out this  
13 paragraph.

14           “(3) Notwithstanding subparagraph (2), prior to the  
15 finalization of regulations to carry out this paragraph, the  
16 use of any claim that a food is ‘natural’ shall be allowed  
17 if consistent with the Secretary’s existing policy for such  
18 claims.

19           “(4) In promulgating regulations to carry out this  
20 paragraph, the Secretary shall differentiate between food  
21 for human consumption and food intended for consump-  
22 tion by animals other than humans.

23           “(5) For purposes of subparagraph (1), a natural  
24 claim includes the use of—

1           “(A) the terms ‘natural’, ‘100% natural’, ‘natu-  
2           rally grown’, ‘all natural’, and ‘made with natural  
3           ingredients’; and

4           “(B) any other terms specified by the Sec-  
5           retary.”.

6 **SEC. 302. REGULATIONS.**

7           (a) PROPOSED REGULATIONS.—Not later than 18  
8           months after the date of enactment of this Act, the Sec-  
9           retary of Health and Human Services shall issue proposed  
10          regulations to implement section 403(z) of the Federal  
11          Food, Drug, and Cosmetic Act, as added by section 301  
12          of this Act.

13          (b) FINAL REGULATIONS.—Not later than 30 months  
14          after the date of enactment of this Act, the Secretary of  
15          Health and Human Services shall issue final regulations  
16          to implement such section 403(z).

17 **SEC. 303. PREEMPTION.**

18          Section 403A(a) of the Federal Food, Drug, and Cos-  
19          metic Act (21 U.S.C. 343–1(a)) is amended—

20                 (1) in paragraph (4), by striking “or” at the  
21                 end;

22                 (2) in paragraph (5), by striking the period and  
23                 inserting a comma; and

24                 (3) by inserting after paragraph (5) the fol-  
25                 lowing:

1           “(6) any requirement for the labeling of food of  
2           the type required by section 403(z) that is not iden-  
3           tical to the requirement of such section.”.

4 **SEC. 304. EFFECTIVE DATE.**

5           The labeling requirements of section 403(z) of the  
6 Federal Food, Drug, and Cosmetic Act, as added by sec-  
7 tion 301 of this Act, shall take effect on the effective date  
8 of final regulations promulgated under section 302(b) of  
9 this Act. The provisions of section 403A(a)(6) of the Fed-  
10 eral Food, Drug, and Cosmetic Act, as added by section  
11 303 of this Act, take effect on the date of enactment of  
12 this Act.

Passed the House of Representatives July 23, 2015.

Attest:

*Clerk.*

114<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

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**H. R. 1599**

**AN ACT**

To amend the Federal Food, Drug, and Cosmetic Act with respect to food produced from, containing, or consisting of a bioengineered organism, the labeling of natural foods, and for other purposes.